



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS 2020-0031]

Mandatory Inspection of Egg Substitutes and Freeze-Dried Egg Products Imported into the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: On October 29, 2020, the Food Safety and Inspection Service (FSIS) published the final rule, "Egg Products Inspection Regulations," which, among other things, announced that FSIS would begin exercising jurisdiction over plants that produce egg substitutes and freeze-dried egg products on October 30, 2023. This notice provides information to foreign countries that already export these products to the United States, as well as countries interested in exporting these products to the United States, about submitting their equivalence documentation to FSIS so that the Agency can begin assessing their eligibility before October 30, 2023.

DATES: Foreign countries currently exporting egg substitutes and/or freeze-dried egg products to the U.S. without an egg products inspection system equivalence determination by FSIS, as well as foreign countries not exporting that are interested in exporting such products to the United States under FSIS jurisdiction:

- Must notify FSIS of their intention to export egg substitutes and freeze-dried egg products to the United States (Phase 1) by October 30, 2021.
- Must submit a complete Self-Reporting Tool (SRT), including supporting documentation that demonstrates how a country's egg products inspection system achieves an equivalent level of public health protection to FSIS' egg products inspection system (Phase 2), by April 30, 2022.
- Must have submitted complete SRT responses and supporting documentation to FSIS, and FSIS must have determined that the SRT submission demonstrates that the country maintains an equivalent documented egg products inspection system to FSIS' egg products inspection system (Phase 3) by October 30, 2023.

Foreign countries that currently maintain equivalent egg products inspection systems to FSIS' inspection system for egg products inspection (i.e., Canada and the Netherlands) must submit an updated certified establishment list to include egg substitutes and/or freeze-dried egg products product groups by October 1, 2023, if these countries are currently exporting these products or wish to begin exporting them to the United States after October 30, 2023.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein,
Assistant Administrator, Office of Policy and Program
Development, telephone (202) 205-0495.

SUPPLEMENTARY INFORMATION: By October 30, 2023, foreign countries that already export egg substitutes and freeze-dried egg products to the United States and wish to continue doing so must have submitted their equivalence documentation to FSIS, and FSIS must have determined that the country maintains an equivalent documented egg products inspection system to FSIS' egg products inspection system. If a country does not submit the required documentation or FSIS has determined that the country does not maintain an equivalent documented egg products inspection system, the foreign country will not be eligible to export egg substitutes and freeze-dried egg products to the U.S. after October 30, 2023. Foreign countries not exporting egg substitutes and freeze-dried egg products that are interested in exporting such products to the United States under FSIS jurisdiction will not be able to begin exporting them until October 30, 2023, after FSIS has determined that the country maintains an equivalent documented egg products inspection system.

On October 30, 2023, egg substitutes and freeze-dried egg products will no longer be regulated by the U.S. Food and Drug Administration (FDA) but instead by FSIS, as they will be recognized as egg products under FSIS' jurisdiction, and FSIS will begin to enforce its regulations regarding the inspection of domestically

produced and imported egg substitutes and freeze-dried egg products (85 FR 68640).

Egg substitutes are similar in formulation, if not identical in some cases, to egg products. Their processing also is like other egg products. The contamination risks associated with these types of products also are identical. For these reasons, FSIS determined that the processing of egg substitutes must take place within the framework of FSIS' Hazard Analysis and Critical Control Point System and Sanitation Standard Operating Procedures framework. Similarly, the food safety risks associated with freeze-dried egg products are like those associated with frozen egg products, as freeze-dried egg products are pasteurized liquid egg products flash frozen and placed in a vacuum chamber where ice particles are removed.

Foreign countries exporting egg substitutes and freeze-dried egg products to the United States, or countries interested in doing so, will need to demonstrate that their documented egg products inspection systems are equivalent to the U.S. system. Foreign countries already exporting egg substitute and freeze-dried egg products to the U.S. may continue to export these products, provided they actively work with FSIS while seeking an initial equivalence determination from the Agency. If they do not submit the required documentation, they will have to stop shipping such products to the United States. The FSIS

equivalency process is described fully on the FSIS website at: <https://www.fsis.usda.gov/inspection/import-export/equivalence>.

Under 9 CFR 590.910(a), whenever it is determined by the Administrator that the system of egg products inspection maintained by any foreign country is such that the egg products produced in such country are processed, labeled, and packaged in accordance with, and otherwise comply with, the standards of the Act and the regulations including, but not limited to the sanitary, processing, facility, and Government inspection requirements in 9 CFR 590.500 through 590.590, notice of that fact will be given according to 9 CFR 590.910(b).

In determining whether a foreign country maintains an equivalent egg products food safety inspection system, the Administrator will review the inspection regulations of the foreign country to determine how the inspection systems are administered in the foreign country. After approval of the inspection system, the Administrator may, as often and to the extent deemed necessary, authorize representatives of the Department to review the foreign inspection system to determine whether it is implemented in a manner equivalent to the U.S. inspection system.

Once FSIS has determined that a foreign country maintains an equivalent egg products food safety inspection system and is eligible to export egg products to the United

States, only establishments that the country's central competent authority (CCA) has certified as complying with the requirements equivalent to U.S. requirements would be eligible to export egg substitutes and freeze-dried egg products to the United States. To ensure that all foreign countries that export, or wish to export, egg substitutes or freeze-dried egg products to the U.S., FSIS is implementing a three-phase plan to assist countries in demonstrating that their documented egg products inspection systems are equivalent to the U.S. system.

During Phase 1, foreign countries that are currently exporting egg substitutes or freeze-dried egg products to the U.S. and do not currently maintain an equivalence determination by FSIS or foreign countries that are interested in exporting such products to the U.S. under FSIS jurisdiction should notify FSIS by October 30, 2021, of their desire to seek an initial equivalence determination for these products. Foreign countries should submit an official notification by email to FSIS' Office of International Coordination at InternationalCoordination@usda.gov. Foreign countries already exporting such products to the United States will be permitted to continue to export these products while seeking an initial equivalence determination from FSIS. In response, FSIS will provide information on how to report necessary information to FSIS through the SRT, which is a

questionnaire used by FSIS to assess whether a country maintains an equivalent documented food safety inspection system.

During Phase 2, foreign countries are requested to submit a complete SRT, including supporting documentation that demonstrates how a country's egg products inspection system achieves an equivalent level of public health protection to FSIS' egg products inspection system, no later than April 30, 2022. FSIS will review the SRT responses and supporting documentation to determine whether additional information is needed from the country. If additional information is needed, FSIS will follow-up with the appropriate CCAs to request additional information. Also, during Phase 2, between April 30, 2022, and April 30, 2023, foreign countries should address any requests for additional information from FSIS and provide updated SRT responses and supporting documentation. During Phases 1 and 2, FSIS will review the SRT submissions and may ask foreign countries for additional information, as needed.

During Phase 3, from April 30 to October 30, 2023, FSIS will continue to review and assess SRT responses and request additional information, if necessary. By the end of Phase 3, October 30, 2023, foreign countries that wish to continue exporting egg substitutes and freeze-dried egg products to the U.S. must have submitted complete SRT responses and supporting documentation to FSIS, and FSIS

must have determined that the SRT submission demonstrates that the country maintains an equivalent documented egg products inspection system to FSIS' egg products inspection system. If the country does not submit the required documentation or FSIS has determined that the country does not maintain an equivalent documented egg products inspection system, the foreign country will not be eligible to export egg substitutes and freeze-dried egg products to the U.S. after October 30, 2023.

Based on its review of the information and documentation that the country submits, FSIS will tentatively decide whether the foreign country's egg products inspection system and requirements are equivalent to FSIS', and if so, plan an onsite audit of the country's egg products inspection system. If FSIS also tentatively finds the foreign country's egg products inspection system equivalent based on the audit, FSIS will advance the equivalence determination through the **Federal Register** notice process announcing the results of the document review and onsite audit, proposing to add the country to its list of eligible exporting countries, and providing an opportunity for public comment. After analysis of public comments, FSIS will publish a **Federal Register** notice announcing its determination on the country's eligibility and responding to comments.

If a country currently maintains an equivalence determination from FSIS for their egg products inspection system, FSIS will request an updated certified establishment list by October 1, 2023, to include these product groups so that countries can continue to export these products to the United States after October 30, 2023. These countries are also required to meet all other requirements of the Egg Products Final Rule.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this *Federal Register* publication on-line through the FSIS website located at: <http://www.fsis.usda.gov/federal-register>. FSIS will also announce and provide a link to it through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, *Federal Register* notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Constituent Update is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at:

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Paul Kiecker,
Administrator.

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